

WHAT IS CLAIMED IS:

1 1. A method for diagnosing, monitoring, or predicting preeclampsia in a
2 pregnant woman, the method comprising the steps of:

3 (i) quantitatively determining the amount of one or more mRNA species in
4 the pregnant woman's blood, wherein the mRNA species are independently selected from
5 mRNA encoding a group of proteins consisting of human chorionic gonadotropin β subunit
6 (hCG- β), human placental lactogen (hPL), human corticotropin releasing hormone (hCRH),
7 KiSS-1 metastasis-suppressor (KISS1), tissue factor pathway inhibitor 2 (TPFI2), placenta-
8 specific 1 (PLAC1), and glyceraldehyde-3-phosphate dehydrogenase (GAPDH); and

9 (ii) comparing the amount of mRNA from step (i) to a standard control
10 representing the amount of mRNA encoding the same protein or proteins in the blood of an
11 average non-preeclamptic pregnant woman, wherein an increase or a decrease in the amount
12 of mRNA from the standard control indicates preeclampsia or an increased risk of developing
13 preeclampsia.

1 2. The method of claim 1, wherein step (i) is performed by reverse
2 transcriptase polymerase chain reaction (RT-PCR).

1 3. The method of claim 1, wherein step (i) is performed by a
2 polynucleotide hybridization method.

1 4. The method of claim 1, wherein step (i) is performed by mass
2 spectrometry.

1 5. The method of claim 1, wherein the woman is during the first trimester
2 of gestation.

1 6. The method of claim 1, wherein the woman is during the second or
2 third trimester of gestation.

1 7. The method of claim 1, wherein the pregnant woman's blood is
2 rendered acellular prior to step (i).

1 8. The method of claim 1, wherein the pregnant woman's blood is plasma.

1 9. The method of claim 1, wherein the pregnant woman's blood is serum.

1 10. The method of claim 1, wherein the increase in the amount of mRNA
2 from the standard control is more than 2-fold.

1 11. The method of claim 1, wherein the mRNA species is mRNA encoding
2 hCRH or GAPDH.

1 12. A kit for diagnosing, monitoring, or predicting preeclampsia in a
2 pregnant woman, the kit comprising:

3 (i) PCR primers for quantitatively determining the amount of one or more
4 mRNA species in the pregnant woman's blood, wherein the mRNA species is independently
5 selected from mRNA encoding a group of proteins consisting of human chorionic
6 gonadotropin β subunit (hCG- β), human placental lactogen (hPL), human corticotropin
7 releasing hormone (hCRH), KiSS-1 metastasis-suppressor (KISS1), tissue factor pathway
8 inhibitor 2 (TPFI2), placenta-specific 1 (PLAC1), and glyceraldehyde-3-phosphate
9 dehydrogenase (GAPDH); and

10 (ii) a standard control representing the amount of mRNA encoding the same
11 protein or proteins in the blood of an average non-preeclamptic pregnant woman.

1 13. A method for detecting the presence of a fetus with trisomy 18 in a
2 pregnant woman, the method comprising the steps of:

3 (i) quantitatively determining the amount of one or more mRNA species in
4 the pregnant woman's blood, wherein the mRNA species is independently selected from
5 mRNA encoding a group of proteins consisting of human chorionic gonadotropin β subunit
6 (hCG- β), human placental lactogen (hPL), human corticotropin releasing hormone (hCRH),
7 KiSS-1 metastasis-suppressor (KISS1), tissue factor pathway inhibitor 2 (TPFI2), placenta-
8 specific 1 (PLAC1), and glyceraldehyde-3-phosphate dehydrogenase (GAPDH); and

9 (ii) comparing the amount mRNA from step (i) to a standard control
10 representing the amount of mRNA encoding the same protein or proteins in the blood of an
11 average pregnant woman with a chromosomally normal fetus, wherein an increase or a
12 decrease in the amount of mRNA from the standard control indicates an increased risk of
13 having a fetus with trisomy 18.

1 14. The method of claim 13, wherein step (i) is performed by reverse
2 transcriptase polymerase chain reaction (RT-PCR).

- 1 **15.** The method of claim 13, wherein step (i) is performed by a
2 polynucleotide hybridization method.
- 1 **16.** The method of claim 13, wherein step (i) is performed by mass
2 spectrometry.
- 1 **17.** The method of claim 13, wherein the woman is during the first
2 trimester of gestation.
- 1 **18.** The method of claim 13, wherein the woman is during the second or
2 third trimester of gestation.
- 1 **19.** The method of claim 13, wherein the pregnant woman's blood is
2 rendered acellular prior to step (i).
- 1 **20.** The method of claim 13, wherein the pregnant woman's blood is
2 plasma.
- 1 **21.** The method of claim 13, wherein the pregnant woman's blood is
2 serum.
- 1 **22.** The method of claim 13, wherein the decrease in the amount of mRNA
2 from the standard control is more than 50%.
- 1 **23.** The method of claim 13, wherein the mRNA species is mRNA
2 encoding hCG β .
- 1 **24.** A kit for detecting the presence of a fetus with trisomy 18 in a pregnant
2 woman, the kit comprising:
3 (i) PCR primers for quantitatively determining the amount of one or more
4 mRNA species in the pregnant woman's blood, wherein the mRNA species is independently
5 selected from mRNA encoding a group of proteins consisting of human chorionic
6 gonadotropin β subunit (hCG- β), human placental lactogen (hPL), human corticotropin
7 releasing hormone (hCRH), KiSS-1 metastasis-suppressor (KISS1), tissue factor pathway
8 inhibitor 2 (TPFI2), placenta-specific 1 (PLAC1), and glyceraldehyde-3-phosphate
9 dehydrogenase (GAPDH); and

10 (ii) a standard control representing the amount of mRNA encoding the same
11 protein or proteins in an average pregnant woman with a chromosomally normal fetus.

1 25. A method for detecting the presence of a fetus with trisomy 21 in a
2 pregnant woman, the method comprising the steps of:

3 (i) quantitatively determining the amount of one or more mRNA species in
4 the pregnant woman's blood, wherein the mRNA species is independently selected from
5 mRNA encoding a group of proteins consisting of human chorionic gonadotropin β subunit
6 (hCG- β), human placental lactogen (hPL), human corticotropin releasing hormone (hCRH),
7 KiSS-1 metastasis-suppressor (KISS1), tissue factor pathway inhibitor 2 (TPFI2), placenta-
8 specific 1 (PLAC1), and glyceraldehyde-3-phosphate dehydrogenase (GAPDH); and

9 (ii) comparing the amount of mRNA from step (i) to a standard control
10 representing the amount of mRNA encoding the same protein or proteins in the blood of an
11 average pregnant woman with a chromosomally normal fetus, wherein an increase or a
12 decrease in the amount of mRNA from the standard control indicates an increased risk of
13 having a fetus with trisomy 21.

1 26. The method of claim 25, wherein step (i) is performed by reverse
2 transcriptase polymerase chain reaction (RT-PCR).

1 27. The method of claim 25, wherein step (i) is performed by a
2 polynucleotide hybridization method.

1 28. The method of claim 25, wherein step (i) is performed by mass
2 spectrometry.

1 29. The method of claim 25, wherein the woman is during the first
2 trimester of gestation.

1 30. The method of claim 25, wherein the woman is during the second or
2 third trimester of gestation.

1 31. The method of claim 25, wherein the pregnant woman's blood is
2 rendered acellular prior to step (i).

1 32. The method of claim 25, wherein the pregnant woman's blood is
2 plasma.

1 33. The method of claim 25, wherein the pregnant woman's blood is
2 serum.

1 34. The method of claim 25, wherein the increase in the amount of mRNA
2 from the standard control is more than 2-fold.

1 35. The method of claim 25, wherein the mRNA species is mRNA
2 encoding hCG β .

1 36. A kit for detecting the presence of a fetus with trisomy 21 in a pregnant
2 woman, the kit comprising:

3 (i) PCR primers for quantitatively determining the amount of one or more
4 mRNA species in the pregnant woman's blood, wherein the mRNA species is independently
5 selected from mRNA encoding a group of proteins consisting of human chorionic
6 gonadotropin β subunit (hCG- β), human placental lactogen (hPL), human corticotropin
7 releasing hormone (hCRH), KiSS-1 metastasis-suppressor (KISS1), tissue factor pathway
8 inhibitor 2 (TPFI2), placenta-specific 1 (PLAC1), and glyceraldehyde-3-phosphate
9 dehydrogenase (GAPDH); and

10 (ii) a standard control representing the amount of mRNA encoding the same
11 protein or proteins in an average pregnant woman with a chromosomally normal fetus.

1 37. A method for diagnosing, monitoring, or predicting pre-term labor in a
2 pregnant woman, the method comprising the steps of:

3 (i) quantitatively determining the amount of one or more mRNA species in
4 the pregnant woman's blood, wherein the mRNA species is independently selected from
5 mRNA encoding a group of proteins consisting of human chorionic gonadotropin β subunit
6 (hCG- β), human placental lactogen (hPL), human corticotropin releasing hormone (hCRH),
7 KiSS-1 metastasis-suppressor (KISS1), tissue factor pathway inhibitor 2 (TPFI2), placenta-
8 specific 1 (PLAC1); and glyceraldehyde-3-phosphate dehydrogenase (GAPDH); and

9 (ii) comparing the amount of mRNA from step (i) to a standard control
10 representing the amount of mRNA encoding the same protein or proteins in the blood of an
11 average pregnant woman who delivers or will deliver at term, wherein an increase or a
12 decrease in the amount of mRNA from the standard control indicates an increased risk of
13 developing pre-term labor.

1 **38.** The method of claim 37, wherein step (i) is performed by reverse
2 transcriptase polymerase chain reaction (RT-PCR).

1 **39.** The method of claim 37, wherein step (i) is performed by a
2 polynucleotide hybridization method.

1 **40.** The method of claim 37, wherein step (i) is performed by mass
2 spectrometry.

1 **41.** The method of claim 37, wherein the woman is during the first
2 trimester of gestation.

1 **42.** The method of claim 37, wherein the woman is during the second or
2 third trimester of gestation.

1 **43.** The method of claim 37, wherein the pregnant woman's blood is
2 rendered acellular prior to step (i).

1 **44.** The method of claim 37, wherein the pregnant woman's blood is
2 plasma.

1 **45.** The method of claim 37, wherein the pregnant woman's blood is
2 serum.

1 **46.** The method of claim 37, wherein the increase in the amount of mRNA
2 from the standard control is more than 2-fold.

1 **47.** A kit for diagnosing, monitoring, or predicting pre-term labor in a
2 pregnant woman, the kit comprising:

3 (i) PCR primers for quantitatively determining the amount of mRNA in the
4 pregnant woman's blood, wherein the mRNA encodes a protein selected from a group
5 consisting of: human chorionic gonadotropin β subunit (hCG- β), human corticotropin
6 releasing hormone (hCRH), human placental lactogen (hPL), KiSS-1 metastasis-suppressor
7 (KISS1), tissue factor pathway inhibitor 2 (TPFI2), placenta-specific 1 (PLAC1), and
8 glyceraldehyde-3-phosphate dehydrogenase (GAPDH); and

9 (ii) a standard control representing the amount of mRNA encoding the protein
10 in an average pregnant woman who delivers or will deliver at term.

1 **48.** A method for detecting pregnancy in a woman, the method comprising
2 the steps of:

3 (i) quantitatively determining the amount of one or more mRNA species in
4 the woman's blood, wherein the mRNA species is independently selected from mRNA
5 encoding a group of proteins consisting of human chorionic gonadotropin β subunit (hCG- β),
6 human placental lactogen (hPL), human corticotropin releasing hormone (hCRH), KiSS-1
7 metastasis-suppressor (KISS1), tissue factor pathway inhibitor 2 (TPFI2), and placenta-
8 specific 1 (PLAC1); and

9 (ii) comparing the amount of mRNA from step (i) to a standard control
10 representing the amount of mRNA encoding the same protein or proteins in the blood of an
11 average non-pregnant woman, wherein an increase in the amount of mRNA from the standard
12 control indicates pregnancy.

1 **49.** The method of claim **48**, wherein step (i) is performed by reverse
2 transcriptase polymerase chain reaction (RT-PCR).

1 **50.** The method of claim **48**, wherein step (i) is performed by a
2 polynucleotide hybridization method.

1 **51.** The method of claim **48**, wherein step (i) is performed by mass
2 spectrometry.

1 **52.** The method of claim **48**, wherein the woman's blood is rendered
2 acellular prior to step (i).

1 **53.** The method of claim **48**, wherein the woman's blood is plasma.

1 **54.** The method of claim **48**, wherein the woman's blood is serum.

1 **55.** The method of claim **48**, wherein the increase in the amount of mRNA
2 from the standard control is more than 2-fold.

1 **56.** A kit for detecting pregnancy in a woman, the kit comprising:

2 (i) PCR primers for quantitatively determining the amount of one or more
3 mRNA species in the woman's blood, wherein the mRNA species is independently selected
4 from mRNA encoding a group of proteins consisting of human chorionic gonadotropin β

5 subunit (hCG- β), human corticotropin releasing hormone (hCRH), human placental lactogen
6 (hPL), KiSS-1 metastasis-suppressor (KISS1), tissue factor pathway inhibitor 2 (TPFI2), and
7 placenta-specific 1 (PLAC1); and
8 (ii) a standard control representing the amount of mRNA encoding the same
9 protein or proteins in an average non-pregnant woman.